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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,382	04/14/2004	Chih-Ping Liu	55600-8014.US01	8686

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EXAMINER	
SNYDER, STUART	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,382	LIU ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *7-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,14-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

37 CFR 1.141. Different inventions in one national application.
(a) Two or more independent and distinct inventions may not be claimed in one national application, ex-cept that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.

Election was made **without** traverse in the reply filed on 10/25/2006. Applicant elected autoimmune disease, which is the subject matter of claims 1-7 and 14-15; claim 1 is generic to autoimmune diseases and claims 6 and 7 are species of the autoimmune diseases. Applicants further elected multiple sclerosis (MS) as the autoimmune species to be examined; claim 6 reads on MS.

Accordingly, claims 7-13 are withdrawn as containing subject matter drawn to non-elected species. Claims 1-6, 14 and 15 are subject to examination. If claim 1 is allowed, claim 7 will be subject to examination. Furthermore, claims 8-13 may be rejoined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-6, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID No.s 2 and 3, does not

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims 1-2, 4-6, 14 and 15, as elected, are drawn to methods of use of **any** isoform of IFN-τ at a daily dose of $5x10^8$ U for treatment of MS. At the time of the invention, it was well known that many isoforms existed (see for example, Alexenko, et al. and references therein) and that there was a range of antiviral activity amongst the isoforms. Alexenko, et al. teaches that the range of activity amongst the various forms of the isoforms can vary up to 500-fold; the two isoforms taught in the specification are in the lower to middle range of the range of activity of the various isoforms (see Table 1, p1338, Alexenko, et al.). Although the particular teaching concerns antiviral activity, it is scientifically reasonable to expect that a similar pattern of variable activity amongst the various isoforms exists for their individual IL-10 modulating activities in as much as the IL-10 modulating activity is a major component of IFN–τ antiviral activity. A skilled artisan would not be able to predict *a priori* at which level a particular IFN–τ would be able to induce an increase in IL-10 blood level while not affecting IFN-g blood level nor inducing intolerable side effects. The specification only teaches IFN–τ1 and IFN–τ2 isoforms in the treatment of MS and there are insufficient working examples of IFN–τ treatment of MS to predict results using other IFN–τ isoforms. The quantity of experimentation necessary to use the claimed invention, especially considering the necessity of relying on human clinical trials, would be excessive. Thus, the full scope of claims 1-2, 4-6, 14 and 15 are not enabled by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is drawn to a method of increasing IL-10/ IFN-γ ratio in subjects suffering from autoimmune condition or viral infection. Claim 1 recites the steps of administering IFN-τ at a specified daily dosage—the limitation to said administration is an increase in blood IL-10 levels accompanied by a stable or decreasing blood level of IFN-γ —and continuing to administer IFN-τ. The critical steps of measuring IL-10 and IFN-γ before and after the initial administration are omitted from the claimed method. Without such measurement, the skilled artisan cannot practice the method as otherwise claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 14-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,083,782 in view of Soos *et al.* Claims 1-6 of the instant application are drawn, as currently restricted, to a drawn to a: method *(i) of increasing IL-10/ IFN-γ ratio in (ii) subjects suffering from MS—(iii) the increase in the ratio is the result of an increase in the blood concentration of IL-10 with concomitant stability or decrease in the blood concentration of IFN-γ— (iv) by oral administration to the (v) digestive tract of (vi) greater than about $5x10^8$ U (vii) per day of (viii) ovine or bovine (ix) IFN-τ (x) having a sequence identified as SEQ ID NO:2 or SEQ ID NO:3, (xi) continuing regular—more than several times per week—oral administration of IFN-τ (xii) until a desired clinical endpoint—(xiii) the reduction of adverse MS symptoms—is achieved, and (xiv) co-administration of a second therapeutic agent (xv) suitable for the treatment of MS.

US Patent No. 7,083,782 teaches a method for treating (ii) multiple sclerosis in a human subject (iv) by oral administration for release (v) to the intestinal tract (vi) of more than about $1x10^9$ U (vii, xi) per day of (viii) ovine or bovine (ix) IFN-τ (x) having a sequence identified as SEQ ID NO:2 or SEQ ID NO:3 (xii) until a desired clinical endpoint is achieved, (xiii) co-administration of a second therapeutic agent (xiv) suitable for treatment of MS. US Pat No. 7,083,782 does not teach (i) increasing IL-10/ IFN-γ

* Lower case Roman numerals refer to the common limitation of the claims.

resulting from (iii) the increase in the blood concentration of IL-10 with concomitant stability or decrease in the blood concentration of IFN-γ.

Soos *et al.* teaches that oral administration of IFN-τ results in sustained (iii) increase in IL-10 levels and stable or decreasing blood levels of IFN-γ resulting in an overall (i) increase of IL-10/IFN-γ ratio (see p 2233, figure 2 and p 2234, column 1, lines 3-11). The subject of Soos *et al.* research was experimentally induced autoimmune encephalomyelitis in mice, a well-accepted small animal model for MS. The dosage schedule used in the study ($1x10^4$-10^5 U/day/20 g mouse) results in administration of ~$5x10^5$-10^6 U/kg body mass whereas the dosage taught in the instant application $1.8x10^8$ administered to 90 kg men results in administration of ~$2x10^6$ U per day/kg body weight; *i.e.,* the dosage schedules are approximately the same and the results are transferable. It is therefore clear that the increase in IL-10/IFN-γ ratio is an intrinsic property of IFN-τ oral administration in subjects being treated for MS and it is proper to combine the post-filing non-patent literature teachings with the teachings of an issued Patent.

Thus US Patent No. 7,083,782 and Soos *et al.* teach all of the limitations of the presently claimed invention; claims 1-6 and 14-15 are properly rejected on the ground of nonstatutory obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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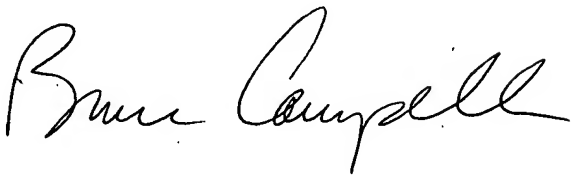

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